

Serial No. 09/726,841

Docket No. 30697

Remarks:

Claims 4, 5, 7-12, and 15 remain for consideration in this application with claims 4, 7, and 11 being in independent format. In view of the claims as they now stand, together with remarks hereunder, the rejections of the Office Action of March 12, 2003 must be traversed.

The present invention provides an improved feeding tube which allows an installer to quickly ascertain whether the tube is properly placed within a patient's esophagus. Generally speaking, the tube comprises an elongated tube presenting a distal end adapted for insertion into a patient and a proximal portion designed to remain outside the patient, a fixture operably coupled with the proximal portion, and one or more intermediate coupling members attached to the fixture. The coupling members are adapted such that they permit the attachment of a CO<sub>2</sub> detecting machine to the tube, and thereby the presence of CO<sub>2</sub> adjacent the distal end of the tube may be detected when the tube is inserted into a patient. Using the present invention reduces the potential of causing damage by unintentionally passing the feeding tube into the respiratory tract.

Claims 4, 5, and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,071,405 to Piontek et al., (Piontek) and claims 4 and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,057,093 to Clegg et al., (Clegg). Claim 4 requires an elongated tube presenting a distal end adapted for insertion into a patient and a proximal portion designed to remain outside the patient, a fixture operably coupled with said proximal portion, and at least one intermediate coupling member attached to said fixture. Piontek simply does not have the required limitations. The Examiner has alleged that Piontek discloses an elongate tube (12) and an intermediate coupling member (22) but has failed to identify any fixture to which the intermediate

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coupling member is operably coupled with as required by claim 4. The intermediate coupling member identified by the Examiner (y-port (22)) is merely a component of the port housing 18 (see column 5, lines 57-63). The port housing (or the portion of it that forms the y-port) cannot be both the intermediate coupling member and the fixture as it is one integral piece which does not suggest having a fixture and an intermediate coupling member. Thus, Piontek does not disclose or suggest a tube having a fixture and at least one intermediate coupling members, as required by claim 4. Without both an intermediate coupling member and a fixture, Piontek would not be adapted for connection to a CO<sub>2</sub> detecting machine. With respect to claim 11, this claim is for a fixture for connection to the proximal end of a feeding tube. The fixture must include a bifurcated body presenting first and second tubular legs. The first leg has a connection end adapted for attachment to said proximal end to form a continuation thereof. The second leg is in communication with the first leg and includes at least one intermediate coupling member adapted for connection with a CO<sub>2</sub> detecting machine. The Examiner has alleged that "a fixture is located at the proximal portion of a feeding tube (12) and the fixture having first and second tubular legs (20, 22), said first leg (20) having a connection end at element 17 and a second leg in communication with said first leg, and an intermediate coupling member considered to be the other end of the first leg which is adapted for connection with a CO<sub>2</sub> detecting machine." However, this does not meet the limitations of claim 11. Comparing Piontek with claim 11, if the first leg is designated by reference numeral 20 and the second leg is designated as reference numeral 22, reference numeral 22 must still have "at least one intermediate coupling member." It cannot be said that the "other end of the first leg" is the first leg

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and the intermediate coupling member. Accordingly, applicant asserts that these rejections have been overcome.

With respect to the rejections of claims 4 and 15 over Clegg, claim 4 has been amended to recite that the fixture comprises a tubular bifurcated body. This limitation was formerly found in claim 5 which was not rejected over Clegg. Clegg does not disclose or suggest a tubular bifurcated body and therefore, it cannot be said that Clegg anticipates claim 4. Accordingly, applicant asserts that this rejection has been overcome.

Claims 7-10 were rejected under 35 U.S.C. 103(a) as being obvious over Piontek in view of U.S. Patent No. 6,258,046 to Kimball (Kimball). These claims have been amended to include the limitation that the CO<sub>2</sub> detecting machine is an end-tidal CO<sub>2</sub> detecting machine. Support for this limitation can be found at page 4, lines 31-36 which define what is meant by CO<sub>2</sub> detecting machine. The definition refers to capnographs and capnometers which are used to detect end-tidal CO<sub>2</sub> and not devices attached to laser-Doppler sensors. The fact that Kimball is not concerned with end-tidal CO<sub>2</sub> is confirmed at column 3, lines 60-64 which disclose that ambient CO<sub>2</sub> levels will not interfere in the tissue perfusion assessment. Such levels are exactly the type of CO<sub>2</sub> levels that an end-tidal CO<sub>2</sub> detector will measure. If the concentration of CO<sub>2</sub> measured by an end-tidal CO<sub>2</sub> detector is too high, a person using the present invention will know that the tube is being improperly placed in the trachea. Accordingly, Kimball actually teaches away from an end-tidal CO<sub>2</sub> detector as required by the claims. Such a machine is not disclosed or suggested by Kimball as none of the devices described by Kimball function (or could function) as end-tidal CO<sub>2</sub> detecting machines. Furthermore, there is no teaching or suggestion to combine Piontek and Kimball as the two devices

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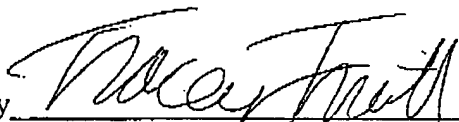
have different functions altogether. Piontek is a surgically placed feeding tube while Kimball detects tissue perfusion. Of course, the teaching or suggestion to combine the references must come from the prior art and not applicant's disclosure and the references cannot be modified in a way that destroys their intended function. In this situation, if the device 30 of Kimball were an end-tidal CO<sub>2</sub> detector, the function of Kimball would be destroyed because Kimball does not want to measure end-tidal CO<sub>2</sub>. Moreover, obvious to try is not the standard for obviousness. Accordingly, the combination of Piontek and Kimball cannot be said to obviate the present invention and applicants respectfully request that this rejection be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned " Version with marking to show changes made."

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Respectfully submitted,

By 

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ATTORNEYS FOR APPLICANT(S)

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**"Version with marking to show changes made."**

**Claims:**

4. (Twice Amended) A patient feeding tube comprising:  
an elongated tube presenting a distal end adapted for insertion into a patient and a proximal portion designed to remain outside the patient;  
a fixture operably coupled with said proximal portion, said fixture comprising a tubular bifurcated body; and  
at least one intermediate coupling member attached to said fixture, said coupling member adapted to permit attachment of a CO<sub>2</sub> detecting machine to the tube so that the presence of CO<sub>2</sub> adjacent said distal end may be detected when the tube is inserted into a patient.
5. (Amended) The feeding tube of claim 4, said tube presenting a proximal end, said [fixture comprising a tubular,] bifurcated body presenting a pair of tubular legs, one of said legs secured to said proximal end, the other of said legs in communication with the interior of said tube.
7. (Amended) A feeding tube and end-tidal CO<sub>2</sub> detecting machine combination comprising:  
an elongated patient feeding tube presenting a distal end adapted for insertion into a patient and a proximal portion designed to remain outside the patient; and  
[a] an end-tidal CO<sub>2</sub> detecting machine operably coupled with said proximal portion of said tube so that the presence of CO<sub>2</sub> adjacent said distal end may be detected when the tube is inserted into a patient.